HYDRAULIC ASSIST METHOD AND SYSTEM

FIELD OF THE INVENTION

The present invention relates to a hydraulic method and a system utilizing the system, useful for various therapeutic purposes associated with various body organs such as, cardiac assist, limb massaging, etc.

BACKGROUND OF THE INVENTION

It is often required to assist a failing body organ in performing its normal sequential operation. Examples of such instances are:

I. A failing heart where cardiac assistance is necessary in case a patient's cardiac output drops below the blood supply required to sustain proper blood perfusion. In such a case a ventricular-assist-device (VAD) is used to bridge a patient until his natural heart recovers, or until a suitable donor heart is found for heart transplantation or as a permanent alternative to heart transplantation. A VAD is useful in complementing or taking over the pumping function of one or both sides of a failing heart by which they unload the assisted ventricle. Several VAD devices and method are known, for example, those disclosed in U.S. Patents Nos. 4,192,293, 5,131,905, 5,429,584, 5,406,422, 5,713,954, 5,800,525, 5,971,910, and 6,508,756.

II. Massaging a limb, e.g. a patient's leg, in case of thrombosis or other vein diseases which are very common among diabetic patients. Massaging the blood vessels, either directly or by applying massaging motion on the

limb may, in many cases, save the limb and prevent it from being amputated.

It is an object of the present invention to provide a hydraulic system and a method utilizing said system for various therapeutic purposes associated with various body organs to thereby stimulate their motion.

SUMMARY OF THE INVENTION

According to the present invention there is provided hydraulic system for supporting a body organ, the system comprising a closed loop liquid-tight tubing fitted with a pressure generator for propelling a liquid through the system, an organ engaging member connected to a pressure chamber via a discharge valve for controlled discharge of liquid into the organ engaging member; said organ engaging member comprising an inflatable pressure member suited for receiving the organ; at least one control valve for selectively controlling liquid flow through the system; and a controller for selectively controlling the discharge valve and the at least one control valve.

According to another aspect of the invention there is provided a method for stimulating motion to a body organ, the method comprising the following steps:

(a) obtaining body-organ hydraulic assist system comprising a pressure generator for propelling a liquid through the system, a pressure chamber, an organ engaging member connected to the pressure chamber and fitted with an inflatable pressure member, valves for selectively controlling liquid flow through the system and for controlled discharge of liquid to the organ engaging member; a controller for selectively controlling the valve means;

(b) fitting the inflatable pressure member over the body-organ; and

(c) activating the pressure generator and the controller.

A principal operating sequence of the system according to the invention comprise charging the pressure chamber, inflating the inflatable pressure member of the organ engaging member to thereby apply a desired pressure on the organ.

Thereafter the pressure member is deflated and the system is ready for a new operating cycle, depending on a particular control algorithm.

The valves are controlled by the controller at a discrete order corresponding with an algorithm suitable for a therapeutic routine and preferably the controller generates control signals responsive to signals corresponding with physiologically-related parameters obtained from the body.

According to a particular embodiment the hydraulic assist method comprises a first one-way valve fitted between the pressure generator and the pressure chamber, a second one-way valve fitted between the organ engaging member and the pressure generator, a pressure discharge valve for controlled discharge of liquid from the pressure chamber into the organ engaging member, and a circulation one-way valve mounted in parallel relation to the pressure generator, on a tube segment extending between the pressure generator and the first one-way valve, and between the second one-way valve and the pressure generator.

According to one embodiment, the method comprises two principal control stages, namely;

(a) a charging stage wherein the pressure discharge valve and the circulating valve are closed, the first valve and the second valve are open, and the pressure generator is active;

(b) a pressure stage wherein the discharge valve is open to thereby facilitate inflating the pressure member, and the circulating valve is open while the pressure generator is active; whilst the first valve and the second valve are closed.

It is however appreciated that a variety of control algorithms are possible for obtaining a sequence of a work cycle as above.

Where the body organ is a heart and the system operates as a cardiac assist system, it is desired that the system operates in cadence with the normal functioning of the heart. In particular, the pressure chamber is charged with pressurized liquid during the diastolic heart period and the organ engaging member is inflated during the systolic period.

The device according to the present invention may be suited for entirely implanting or partially implanting, where at least the organ engaging member is transplanted and other components are externally retained.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, some embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which:

Fig. 1 is a schematic representation of a system according to the present invention;

Fig. 2 is a *time/volume* graphic representation of a cycle of a failing heart superimposed with the performance with a system according to the present invention;

Figs. 3A and **3B** are schematic representations of the principal control stages of a system according to an embodiment of the present invention; and

Figs. 4A to **4E** are schematic representations of a specific control algorithm of a system according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Attention is first directed to Fig. 1 of the drawings illustrating a system in accordance with the present invention, generally designated **10** which will be hereinafter exemplified in connection with a cardiac-assist-device (CAD) and comprising a primary pipe circuit generally designated **12** and a secondary pipe circuit generally designated **16**. The primary pipe circuit comprises a pressure generator **20** which is a hydraulic pump designed to operate at low flow rates and suited for continuous and long lasting operation. Pressure generator **20** is fitted with a power source e.g. battery **21**. However, it should be appreciated that other forms of power source may be used, such as, an external battery (where power is supplied by suitable conductive means) or an internal battery chargeable by externally applied induction, etc.

Preferably, a non-expandable/non-inflatable pipe segment **24** communicates between the pressure generator **20** and a first valve **26** which is a one-way valve admitting flow only in a flow direction illustrated by arrows **28**. Valve **26**, like all other valves in the system is controlled by a controller **C** communicating therewith by means of control lines illustrated in Fig. 1 by dashed lines.

First valve **26** is in flow communication with a pressure chamber **30** which is a pressurized liquid accumulator, for example, made of a container having considerably elastic walls, e.g. silicon or a metallic membrane deformable between a constricted position and an expanded, pressurized position.

Downstream of the pressure chamber **30** there is provided a discharge valve designated **34** which is also a one-way valve permitting flow only in the direction of arrows **28** and which is also controlled and governed by controller **C** as will be apparent hereinafter.

An organ engaging member **40** comprises a casing **42** made of a rigid, non-deformable material and accommodating an inflatable pressure member **46** being in flow communication with the discharge valve **34**. The inflatable pressure member **46** is made of a pliable/flexible material and it is not necessary for the inflatable pressure member to be elastic. The inner shape of the inflatable pressure member corresponds with the shape of the concerned organ. Inflating the pressure member **46** entails inward radial constriction of space **48**.

The inflatable pressure member **46** is further in flow communication with a second valve **52** which is a one-way discharge valve also controllable by controllable **C** and which is in flow communication via a return pipe segment **54** with the pressure generator **20**.

The secondary pipe circuit **16** comprises a pipe segment **56** extending between pipe segments **24** and **54** with a circulating valve **60** mounted thereon and controllable by controller **C**. Circulating valve **60** is a one-way valve allowing flow only in the direction of arrows **64**, i.e. in collaboration with the flow through the primary pipe circuit **12**.

Typically, all the components of the system are biologically acceptable and are made of approved material. Furthermore, the piping segments are preferably made of essentially non-elastic material to thereby prevent undesired pressure loss at some regions of the system and to prevent wearing of the mechanical components.

The liquid flowing through the system is a physiological acceptable solution so that in case of leakage no harm is caused.

In practice, the device may be completely implanted into a body, e.g. in case of a cardiac assist device wherein the heart is cradled within the organ engaging member. However, at times, and depending on the organ concerned, it may be appropriate that some of the components of the system, e.g. pressure generator **20** with its power supply **21** and controller **C** be externally attached for maintenance and performing different functions.

The controller **C** may be a programmable controller and may even be associated with an ECG device so as to change the performance of the system depending on physiological parameters of the patient.

Further reference is directed also to Figs. 3A and 3B wherein like elements as in Fig. 1 were given the same reference numbers. A work cycle comprises a sequence of two principal stages, namely a charging stage (Fig. 3A) and a pressure stage (Fig. 3B).

At the charging stage of Fig. 3A the inflatable pressure chamber **46** is drained (by opening second valve **52**) and discharge valve **34** and the circulating valve **60** are closed and the first valve **26** is open, such that pressure generated by pressure generator **20** is charged into the pressure chamber **30** which act as an accumulator. Upon completing the charging stage, the controller **C** (Fig. 1) switches the system into to the pressure stage as in Fig. 3B. In this stage the second valve **52** and the first valve **26** are closed, whilst the discharge valve 34 is opened so as to facilitate discharging the pressure chamber **30** and inflating the inflatable pressure member **46** of the organ engaging member **40**. Further at this stage, the circulating valve **60** opens, so as to circulate the working liquid through the

secondary pipe circuit **16** (Fig. 1) whilst the pressure generator **20** continues to work.

The two principal stages of Figs 3A and 3B are continuously repeated in cadence with the self pace of the heart. Accordingly, the charging stage (Fig. 3A) will typically occur during a diastolic heart period (Fig. 2), and the pressure stage (Fig. 3B) will occur during the self systolic operation of the heart (corresponding with lines I in Fig. 2).

It is preferable that the system is continuously controlled and governed by physiological parameters in accordance with the physiological condition of the heart, as mentioned hereinabove and as known in the art.

Whilst the system has been described and disclosed with reference to a cardiac device, it should be obvious to a skilled person that the system may also be used for assisting other organs, e.g. massaging blood vessels in limbs, etc.

A somewhat different control algorithm is illustrated in Figs 4A to 4E wherein for sake of clarity like elements as in Figs. 1 and 3A and 3B were given the same reference numbers.

At the initial stage of Fig. 4A inflatable pressure member **46** is deflated (un-pressurized) whilst the pressure chamber **30** is charged (under pressure). The valves **26**, **34** and **52** are in closed position and circulation valve **60** is open to thereby facilitate circulation in secondary pipe circuit **16** by means of pressure generator (pump) **20**. At the next step (Fig. 4B), discharge valve **34** is opened whereby liquid. After the pressure stage of Fig. 4B, discharge valve **34** closes again (Fig. 4C). Then, valve **52** opens to drain (deflate) the pressure member **46,** valve **26** opens and valve **60** closes whereby liquid now flows to the pressure chamber **30** (Fig. 4D). Finally, valve **52** closes (Fig. 4E) and upon completing charge of the pressure chamber **30**, the system is now ready for a new sequence beginning at Fig. 4A.

In order to avoid excessive heat built-up and excessive wear of the system, it is desirable that either the first valve or the circulation valve be open, while the

pump/pressure generator is active. A possible alternative may be halting pressure generation while both said valves are closed.

Whilst two particular examples of control algorithms have been disclosed herein above, it is to be appreciated that other control algorithms may be utilized to obtained a controlled sequence of operation according to various operating patterns. For example, valves may be opened/closed simultaneously rather than in series, etc.

Furthermore, it is apparent that other modifications of the device are possible, such as use of other forms of power source, etc. Evermore so, the device may be suited for entirely implanting or partially implanting, where at least the organ engaging member is transplanted and other components are externally retained.